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10/522,324	01/25/2005	Michael Birsha Davies	PG4886-A USW	9221

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EXAMINER	
MATTER, KRISTEN CLARETTE	

ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
08/05/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/522,324	DAVIES, MICHAEL BIRSHA	
	Examiner	Art Unit	
	KRISTEN C. MATTER	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/25/04 and 2/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *WO 01/68169*.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 2, 7, 8, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, in line 2, the limitation "comprises only at least one further medicament dispenser" is confusing because only one medicament dispenser is ever discussed in the specification. Should "dispenser" be changed to --container--?

Regarding claims 7 and 10, in line 2, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Examiner suggests removing the term "such as."

Claim 8 is dependent on claim 7 and is therefore rejected for the reasons outlined above with respect to claim 7.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 16-22, 27-31, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Haber et al. (US 5,524,613).

Regarding claims 1, 2, 27, 28, and 31, Haber et al. discloses a powder inhaler comprising first and second medicament containers (390A, 390B) having first and second release means (393, 394), wherein the first and second components are kept separate from each other until the point of release for inhalation and at least one actuation indicator (either by visually seeing the activation cap 300 compressed towards the reservoir cap 401, through lens 400, or through the contrasting colors of the dosing members). The containers each contain different medicaments (column 2, lines 20-25).

Regarding claims 3 and 4, the actuation indicator can be considered to act directly (lens 400 or contrasting colors -- see column 2, lines 40-45) or indirectly with the containers (compression of the caps).

Regarding claim 5, the lens (400) allows a user to see that medicament from both containers has been released (see column 9, lines 60-65).

Regarding claims 6-8, the dose compartment (394) acting on the first container (and the ability for a user to see that medicament has been released) can be considered a single actuation indicator that acts on the first container only, and the first and second containers can be considered coupled through the inhaler body/caps (i.e., actuator coupling/lever) so that actuation of the first container enables release of medicament from both containers.

Regarding claim 9, the holes in the activation cap (300) (see Figure 8) can be considered the fixing means.

Regarding claims 10 and 11, Haber et al. discloses bulk reservoirs with moveable metering means (391, 392, 393, 394).

Regarding claims 16-18, the pressing together of the caps causes medicament to be placed into each dose compartment which can be visually seen by a use (i.e., actuation indicator) and can be considered an actuation step or a pre-actuation step (i.e., medicament must still be inhaled by the user). In addition, the compression of the caps themselves (and a user visually seeing the two caps closer together) can be considered an actuation or pre-actuation step.

Regarding claims 19-22, each container has a dosing compartment that is visible through the lens (400) and can be considered a separate actuation indicator.

Regarding claims 29 and 30, Haber et al. discloses a single outlet (350) upon which a user inhales to cause the medicaments to be delivered to the respiratory tract.

Regarding claim 37, Haber et al. discloses a method of treating a respiratory disorder by inhalation from a dispenser having the same structure as claimed in claim 1.

Claims 1, 3-5, 19-32, and 37 are rejected under 35 U.S.C. 102(b) as being anticipating by Trueba (US 6,684,880).

Regarding claims 1, 27, 28, and 31, Trueba discloses an inhaler comprising first and second medicament containers (50-56) having first and second release means (40-46), wherein the first and second components are kept separate from each other until the point of release for inhalation and at least one actuation indicator (column 7, lines 1-10). The containers each contain different medicaments (column 3, line 1). In addition, Trueba discloses that each container can be individually activated by manually pressing an activation button (column 4, line65-column 5, line 5, column 6, lines 35-40, and column 11, lines 5-20). Visually seeing the depression of the actuation button (as defined by the specification on page 5 as "any means for indicating when the

dispenser device is actuated) can be considered an actuation indicator as well as the signal from the pressure sensor (column 6, lines 40-50).

Regarding claim 3, the display on the inhaler itself can be said to associate directly with the container.

Regarding claim 4, the display from the remote computer (15) on which all information relating to the inhaler can be uploaded, downloaded, and/or stored can be considered to associate indirectly with the containers.

Regarding claim 5, the display (105) associates with all containers.

Regarding 19, the manual buttons for activating each container (and the visual of the buttons being depressed) can be considered an actuation indicator for each container.

Regarding claims 20-22, depression of a manual buttons to release a selected dose from each container can be considered an actuation step or a pre-actuation step (i.e., a user must still inhale the medicament).

Regarding claims 23-25, Trueba discloses a pressure sensor for sending a signal to the controller to release the medicament upon determination of inhalation from a user and also measures how much medicament has been released from the containers (column 6, lines 50-65).

Regarding claim 26, Trueba discloses display (105) that indicates the remaining doses (column 7, lines 1-5).

Regarding claims 29 and 30, Trueba discloses a single outlet (35) for delivery of the medicament in response to the inward breath of a patient.

Regarding claim 32, Trueba discloses bronchodilators and anti-inflammatories as possible medicaments held in the containers (column 4, lines 14-16).

Regarding claim 37, Trueba discloses a method of treating a respiratory disorder by inhalation from a dispenser having the same structure as claimed in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. Haber et al. does not disclose the specifically claimed medicaments. However, absent a critical teaching and/or a showing of unexpected results from using the specifically claimed medicaments, examiner contends it would have been an obvious design consideration to one of ordinary skill in the art at the time of the invention to have used the well known and commonly used claimed medicaments in the device of Haber et al. for treating various respiratory disorders with inhalation therapy. Furthermore, it appears as though the device of Haber et al. would perform equally well if used with the claimed medicaments.

Claims 2 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trueba.

Regarding claim 2, Trueba discloses multiple containers. To the extent, if any, that Trueba is silent as to there being only two containers, examiner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to have used only two

containers in order to treat respiratory diseases with a combination therapy of two medicaments. In addition, it appears as though the device disclosed by Trueba would perform equally well with only two containers.

Regarding claims 33-35, Trueba does not disclose the specifically claimed medicaments. However, absent a critical teaching and/or a showing of unexpected results from using the specifically claimed medicaments, examiner contends it would have been an obvious design consideration to one of ordinary skill in the art at the time of the invention to have used the well known and commonly used claimed medicaments in the device of Trueba for treating various respiratory disorders with inhalation therapy. Furthermore, it appears as though the device of Trueba would perform equally well if used with the claimed medicaments.

Claims 1-3, 5-7, 9, 12, 14, 27-35, and 37 are rejected under 35 U.S.C. 103(a) as being obvious over UNC Chapel Hill (WO 01/68169, herein referred to as "UNC").

Regarding claims 1, 27, 28, and 31, UNC discloses a powder inhaler comprising first and second medicament containers (Figures 5A-5C) with first and second release means (25, 26 -- each container has it's own pad for vibrating the contents of the blister to promote release), wherein the first and second medicaments are different and kept separate for each other until the point of delivery (page 22, lines 1-10). The device also includes at least one actuation indicator (extension member 172 is visually depressed when actuated). To the extent, if any, that UNC does not disclose use of the blister packs seen in Figures 5 or 6 with the inhaler device of Figure 11, examiner contends it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the blister pack seen in Figures 5 or 6 of UNC in the inhaler device

of Figure 11 in order to deliver combination therapy to a patient with a respiratory disorder using the inhaler of Figure 11.

Regarding claim 2, UNC does not disclose a single use device with only two medicament containers. However, absent a critical teaching and/or a showing of unexpected results from having only one other medicament container, examiner contends it would have been an obvious design consideration to one of ordinary skill in the art at the time of the invention to have had only two containers so that the device could be used as a single dose device instead of being reusable to avoid contamination problems.

Regarding claims 3 and 5, to the extent that UNC does not specifically state that the extension member (172) associates directly with both containers seen in Figure 5, examiner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to have had a single extension member associate with both containers to be delivered so that the combination of drugs could be placed in the operative position for simultaneous delivery.

Regarding claims 6, 7, and 9, UNC does not disclose how the extension member would operate on the second container. However, because the containers are coupled via the blister pack body, examiner contends it would have been obvious to one of ordinary skill in the art for the extension member to line up with only one of the containers for placing the container into the operating position, with the second respective container being placed into position by virtue of the associated blister pack backing in order to allow both medicaments to be delivered simultaneously.

Regarding claims 12 and 14, UNC discloses that the inhaler has a dose access coupling and dose advancement means that rotates the blister pack and places the next container in line for actuation (column 11, lines 20-30).

Regarding claims 29 and 30, UNC discloses a single outlet (11) that delivers medicament upon inhalation by a user (column 14, lines 60-65).

Regarding claims 32-35, UNC does not disclose the specifically claimed medicaments. However, absent a critical teaching and/or a showing of unexpected results from using the specifically claimed medicaments, examiner contends it would have been an obvious design consideration to one of ordinary skill in the art at the time of the invention to have used the well known and commonly used claimed medicaments in the device of UNC for treating various respiratory disorders with inhalation therapy. Furthermore, it appears as though the device of UNC would perform equally well if used with the claimed medicaments.

Regarding claim 37, UNC discloses a method of treating a respiratory disorder by inhalation from a dispenser having the same structure as claimed in claim 1.

Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over UNC as applied to claims 1-3, 5-7, 9, 12, 14, 27-35, and 37 above, and further in view of Casper et al. (US 2007/0181124). To the extend, if any, that UNC does not disclose each container comprising a pack, Casper et al. is cited to show that it is well know to combine separate medicines onto a single pack for simultaneous delivery by using two separate packs, each with a different medicine contained in the blisters (see Figures 10-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the

separate containers of UNC on separate packs as taught by Casper et al. for manufacturing ease or to allow different and user selectable combinations of medicaments.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-35 and 37 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 and 38 of copending Application No. 10/522,319. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claims and the instant claims are minor and obvious from each other. For example, the instant claim 1 is a broader version of the copending claim 1 (i.e. the instant claim 1 does not include the structural element of the electronic control means as in the copending claim 1). In the instant claim 1, the structural elements are included in (or obvious in) the copending claim 1. Any infringement over the

copending application would also infringe over the instant claims. Hence, the instant claims 1-35 and 37 do not differ from the scope of the copending claims 1-36 and 38.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-35 And 37 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/502,405. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claims and the instant claims are minor and obvious from each other. For example, the instant claim 1 is a broader version of the copending claim 1 (i.e. the instant claim 1 does not include the structural element of the specific medicaments as in the copending claim 1). In the instant claim 1, the structural elements are included in the copending claim 1. Any infringement over the copending application would also infringe over the instant claims. Hence, the instant claims 1-35 and 37 do not differ from the scope of the copending claims 1-37.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-35 and 37 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 9-22 of copending Application No. 10/523,121. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claims and the instant

claims are minor and obvious from each other. For example, the instant claim 1 is a broader version of the copending claim 1 (i.e. the instant claim 1 does not include the structural element of the mechanically coupled release means as in the copending claim 1). In the instant claim 1, the structural elements are included (or obvious in) in the copending claim 1. Any infringement over the copending application would also infringe over the instant claims. Hence, the instant claims 1-35 and 37 do not differ from the scope of the copending claims 1-7 and 9-22.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771